DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

BUFFALO DISTRICT
Food and Drug Administration
599 Delaware Avenue
Buffalo, NY 14202

1 November 1996

WARNING LETTER BUF 97-2

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Phillip H. Van Leishout
Brabant Farm
6166 Happy Valley Road
Verona, New York 13478

Dear Mr. Van Leishout:

Two tissue residue reports from the United States Department of Agriculture (USDA), an inspection of your dairy farm, and related investigations by Food and Drug Administration (FDA) Investigator William P. Chilton revealed serious violations of the Federal Food, Drug and Cosmetic Act (the Act).

A food is adulterated within the meaning of Section 402(a)(2)(D) of the Act if it contains a new animal drug which is unsafe within the meaning of Section 512 of the Act. On or about 20 May 1996 you sold a cow, identified by sale tag #517, back tag #21HT2511, and USDA Domestic Laboratory Report #349650, for slaughter for human food. USDA analysis of the tissue from the animal revealed the presence of .25 ppm Penicillin in kidney tissue, 1.5 ppm Streptomycin in kidney tissue, and 1.2 ppm Streptomycin in liver tissue. On or about 3 June 1996 you offered a second cow, identified by sale tag #738, back tag #21HT2743, and USDA Domestic Laboratory Report #348671, for slaughter for human food. USDA analysis of the tissue from the animal revealed the presence of .88 ppm Penicillin in kidney tissue and .10 ppm in liver tissue. These levels exceed the 0.05 ppm tolerance for Penicillin and 0.50 ppm tolerance for Streptomycin in cattle and cause the food to be adulterated.

A food is also considered adulterated within the meaning of Section 402(a)(4) of the Act if it has been held under conditions whereby it may have been rendered injurious to health. You hold animals under conditions which are so inadequate that medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you fail to maintain permanent and complete treatment records and a system to review such records prior to offering cattle for slaughter for human food; to assure drugs have been used only as directed and if needed; extended withdrawal periods have been observed to permit depletion of potentially hazardous residues of drugs from edible tissues. Food from animals held under such conditions is adulterated.

You are adulterating the drug Pen-Aqueous Sterile Penicillin G Procaine Suspension, which you use on cattle, within the meaning of Section 501(a)(5), when you fail to use the drug in conformance with its approved labeling. Your use of the drug at higher than labeled dosages causes the drug to be unsafe to use.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for assuring your overall operation and the foods you distribute are in compliance with the law.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Federal Food, Drug and Cosmetic Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for violation of the Act.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure, and/or injunction.

Please notify this office, in writing, within 15 days of the specific steps you have taken to bring your firm into compliance with the law. Your response should include each step taken, or to be taken, to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 days, state the reason for the delay and time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.
Your reply should be directed to:

Joseph H. Erdmann, Team Leader
U S Food and Drug Administration
PO Box 7197
250 South Clinton Street - Suite 601
Syracuse, New York 13261.

Sincerely,

E. Pitt Smith
District Director

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cc: [redacted]